

Study Title: Developing SUPPORT, A community-driven, recovery-oriented system of care

Document: Informed consent form

Document Date: 9/26/17

ID: 1511731907

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Developing SUPPORT, a Community-Driven, Recovery-Oriented System of Care

You are invited to participate in a pilot research study of Substance Use Programming for Person-Oriented Recovery (SUPPORT). You were selected as a possible participant for this study because you are eligible for services at Public Advocates in Community Re-entry (PACE) in Indianapolis, Indiana, are at least 18 years of age, have a substance use disorder, are no longer incarcerated (in prison, jail, or work release facility), and are unable to access the Indiana Recovery Works program. We will walk through this form together and please ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Dennis P. Watson, at the IU Richard F. Fairbanks School of Public Health and The Center for Health Policy, and Dr. Brad Ray, at the IU School of Public and Environmental Affairs. It is funded by National Institutes on Drug Abuse (NIDA).

STUDY PURPOSE

The purpose of this study is to test SUPPORT as a type of care for substance use services to understand how it impacts the participants.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

We plan to collect data from individuals who are: eligible for services at PACE, are at least 18 years of age, have a substance use disorder, are no longer incarcerated (in prison, jail, or work release facility), and are unable to access the Indiana Recovery Works program. If you take part in the study, you will be one of 80 clients (40 SUPPORT; 40 treatment as usual).

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will be randomly placed in (1) the SUPPORT program **or** (2) regular treatment at PACE.

- (1) If you are assigned to the SUPPORT program, you will receive voucher-based care coordination (i.e. additional money to cover services) for 12 months in addition to the regular services at PACE, and you'll be assigned a recovery coach who will help you select services that are most helpful in meeting your personal goals.
- (2) If you are assigned to regular treatment at PACE, you will receive all usual treatment services provided by PACE.

Regardless of which group you are randomly assigned to, we will also ask you to participate in data collection for the study, for which you will receive compensation.

Both study groups will be asked to:

- Participate in a computer-assisted interview.
 - The interview will last between 1 and 2 hours depending on how fast we are able to move through the questions.
 - During this interview, we will ask you questions, using a computer, about your: demographic & background information (date of birth, gender, race, ethnicity, sexual orientation, military involvement), drug and alcohol use, family and living conditions, education/employment/income, history of crime and criminal justice involvement, physical/mental health, and social support.
- We will also ask about your self-determination (i.e. how you feel about achieving goals or controlling your own life); treatment motivation; self-efficacy (i.e. how capable you feel or how you approach your goals); substance use frequency, quality of life, and unprotected sexual activity.

In the last set of questions, we will ask you about social support. You will be asked about people you interact with on a regular basis. We will only ask you to identify these people by their first name and last initial so that they cannot be identified by the researchers. We will also ask you to describe these people and how you are connected to them.

- We will ask you to complete this interview, and each set of questions, at the beginning of your treatment and again 6, and 12 months following (or when you leave the program, if that is earlier than 12 months). Each interview will last approximately the same amount of time (1-2 hours).

If you are assigned to the SUPPORT program, you may also be asked to:

- Participate in an additional computer-assisted interview at 15 months.
- Participate in a final focus group where:
 - A researcher will ask you about your experience in the SUPPORT program.
 - We will ask you to participate in this interview approximately 15 months after beginning treatment. This interview will last approximately 45-60 minutes.

All interviews will be carried out either in the PACE facility at a time that works best for you.

When you are discharged from the program at PACE, we will ask PACE staff for the following information 1) when you were discharged from the program and 2) why you were discharged from the program. Reasons for discharge may include: program completion/graduation and program termination (i.e. you leave the program for some other reason than program completion.)

RISKS OF TAKING PART IN THE STUDY

Potential risks of taking part in this study include:

- You may get tired or bored due to the length of time it takes to complete the interviews.
- You may feel uncomfortable answering questions about people you interact with.
- You may experience discomfort due to the sensitive nature of some of the questions pertaining to: your personal background, employment and education history, past involvement in treatment, self-determination (i.e. how you feel about achieving goals or controlling your own life), treatment motivation, social support/networks, self-efficacy(i.e. how capable you feel or how you approach your goals) , and frequency of substance use, treatment readiness, and treatment experiences/relationships/outcomes.
- You may experience discomfort or concern answering questions about illegal drug use.
- People you interact with may become upset if they learn you spoke about them in the interview.
- The information you share electronically may be stolen or hacked.
- The contact information we collect could be used to identify you or someone you know.
- You may feel as though your decision to participate will affect your status as a PACE client.

In order to minimize these risks:

- Researchers will not share any individual information you provide with PACE staff.
- You can take a break at any point in the interview you wish.
- All interviews will take place in a private location so that others will not overhear information discussed.
- You may choose not to answer any questions you are not comfortable with.
- Information you share about illegal drug will be kept private. PACE does not share information you share regarding drug use with any part of the criminal justice system. We have obtained a Certificate of Confidentiality from the National Institutes of Health, which prevents any attempts by the criminal justice system to subpoena the data (i.e. order that they receive the data).
- We are only asking for the first name and last initial of people you interact with, and we will not follow up with them after the interview.
- Data will be collected using a secure data collection and management system.
- The only information linking your name with the answers you provide during the interview will be a unique identification number. The list of names and identifiers will be kept on a password protected

computer linked to a secure network. Only Dr. Watson will have access to this list of identifying information.

- We have developed additional review procedures to assure the data you provide us is secure.

BENEFITS OF TAKING PART IN THE STUDY

The benefits to participation that are reasonable to expect for the individual are:

- The opportunity to inform support services for substance use disorders.
- The opportunity to reflect on recovery and relationships with others.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Participation is completely voluntary. You are under no obligation to complete participant if you agree to be contacted.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. We will not be recording any names on the interview itself. Interviewers will only record a subject identification number on the electronic form. All contact information will be collected on a separate paper form so that it cannot be linked with interview answers. A key linking subjects' names to the identification number will stored on password protected network, and only research staff on this project will have access to the file. PACE does not share information you share regarding drug use with any part of the criminal justice system.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, the National Institutes on Drug Abuse, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your research records.

PAYMENT

Both study group participants will receive compensation for the interviews.

- Participants will receive \$60 in gift cards for each electronic interview you complete (baseline, 6 months, 12 months).
- Additionally, you will be entered in a drawing to win one of two \$100 VISA gift cards if you complete the interview.

If you are randomly enrolled in the SUPPORT program and asked to complete the additional focus group (15 months), you will receive a \$30 gift card for participating. You will also receive an additional \$60 for completing the 15 month CAPI that will be asked of SUPPORT clients only.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact Dr. Dennis Watson at (317) 278-5907. For questions about your rights as a research participant, to discuss concerns about a research study, to obtain information, or to offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Deciding not to participate or leaving the study will not result in any penalty or loss of benefits and will not affect your current or future relations with PACE.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name: _____

Subject's Signature: _____

Date: _____ (must be dated by the subject)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: _____